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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,054	10/12/2001	George L. Mutter	B0801/7234	1813

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EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,054

Applicant(s)

MUTTER, GEORGE L.

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/28/02; 1/3/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Applicant's election of Group III, claims 19-24 in the response filed 2/4/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 2/4/04.

Information Disclosure Statement

The IDS's filed 3/28/02 and 1/3/03 have been considered in full.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites a method of classifying an unknown tissue, then recites a series of steps culminating with a comparison step. No actual step of classification is recited in the claims, therefore it is unclear if applicant actually intends a method of classification

or merely intends a method of comparing tissues based on variable values. As it is unclear what method applicant intends, the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by ROTHBERG et al. (US 5,871,697).

ROTHBERG teaches a method of classifying an unknown tissue by comparing gene expression data from nondiseased tissues and diseased tissues (i.e. index and contrast tissues), and using the data from the comparison to determine whether an “unknown” or unclassified tissue is diseased or a particular stage of disease; i.e. by ranking of data *col. 23, line 30-col. 24, line 30). ROTHBERG teaches that his comparison may be statistical and specifically teaches use of an average and standard deviation for each of individual signals to compare and classify tissues (col. 37, lines 15-39), thus anticipating claims 19 and 23-34. ROTHBERG teaches visual display of his results to a user (col. 79, lines 27-47), thereby anticipating claim 20.

Claims 19-21 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by GOLUB et al. (US 6,647,341, filed 4/6/00).

GOLUB teaches a method of classifying an unknown tissue by comparison of gene expression patterns of the "unknown" to gene expression patterns of normal versus diseased tissue. GOLUB teaches that his gene expression patterns comprise an average and standard deviation of gene expression values, teaches that his data is ranked (e.g. by density), and that comparison of the "unknown" may be made using his rankings (col. 2, lines 20-60), thereby anticipating claims 19 and 23. GOLUB teaches a visual display of his data and teaches that data from different tissues may be "coded" (see Figures 3, 5 and 7), thus anticipating claims 20-21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over ROTHBERG et al. (US 5,871,697).

Claim 19 recites a method of classifying an unknown tissue comprising measuring the values of each variable of a set of variables for an index set of tissues and a contrast set of tissues, calculating a mean and difference from the mean for

each variable, ranking the means and differences between the index group and contrast groups of tissues, measuring variables in an unknown tissue, and comparing the measurements from the unknown tissue to the ranked data to classify the unknown tissue. Claim 20 limits the method to further comprise a step of displaying the results. Claim 21 limits the display to one wherein symbols are coded based on positive and negative values of means and differences from a mean. Claim 23 limits the variables to genes and the values measured to levels of gene expression. Claim 24 limits method to one wherein values are expressed as a log of gene expression.

ROTHBERG teaches a method of classifying an unknown tissue by comparing gene expression data, as set forth above. ROTHBERG does not specifically teach showing his data as a log of gene expression, nor does ROTHBERG specifically teach coding symbols for display.

It would have been obvious to one of ordinary skill in the art at the time of invention to have coded symbols according to negative or positive values in the display of data taught by ROTHBERG where the motivation would have been to make it easier for a user to interpret the results, as suggested by ROTHBERG's teaching for automating visual comparison of data by performing statistical analysis of signals (col. 79, lines 38-45). It would further have been obvious to have shown gene expression data in log format where the motivation would have been to use a statistical format which allows for ease of graphing (e.g. to accommodate a large range of numbers on a single axis), and where expressing statistical data in log format is well known in the art. One skilled in the art would reasonably have expected success in using symbols

and a log format in the display of ROTHBERG because ROTHBERG teaches both analysis and display of statistical analysis results.

Claim 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over ROTHBERG et al. (US 5,871,697), as applied to claims 19-21 and 23-24 above, further in view of SUGA et al. (IDS ref: US 5,739,808).

The claims recite a method of classifying an unknown tissue, as previously set forth. Claim 22 limits the display to a ternary display.

ROTHBERG teaches and makes obvious a method of classifying an unknown tissue, as previously set forth. ROTHBERG does not teach a ternary display.

SUGA teaches that a ternary display is a high resolution display which can be used to display any kind of data results (col's 7-8).

It would have been obvious to have displayed the data results of ROTHBERG as a ternary display, as taught by SUGA, where the motivation would have been to use a high resolution display in order to better visualize the data, as suggested by SUGA's teaching that a ternary display has better resolution than other types of display.

Conclusion

Claims 19-24 are rejected; claims 1-10 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571)

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272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mam

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
4/8/04